

REMARKS

In the aforesaid Office Action, the specification and claim 5 were objected to, claims 4 and 5 were rejected under 35 USC 112, second paragraph, claims 1-8 and 10 were rejected under 35 USC 102(e) as anticipated by Elliot (US 2003/0164063), and claims 9 and 11 were rejected under 35 USC 103(a) as being unpatentable over Elliot alone. Claims 1-11 are pending (claims 12-45 are cancelled by this amendment).

The Examiner required a restriction to one of the following inventions under 35 USC 121:

- I. Claims 1-11;
- II. Claims 12-17;
- III. Claims 18-26;
- IV. Claims 27-34;
- V. Claims 35-45.

Applicants hereby affirm election of group I, claims 1-11.

The Examiner objected to the use of uncapitalized trademarks in the specification.

Applicants have amended paragraph [0019] to obviate the objection.

The Examiner objected to claim 5, stating that “MA-g-PO” should be written out.

Applicants have amended claim 5 to obviate the objection. Support for the amendment to claim 5 can be found in paragraph [0011].

The Examiner rejected claims 4 and 5 under 35 USC 112, second paragraph, stating that the limitation “Pebax” in claim 4 is a trademark which cannot be properly used to identify a material, and “said multi-functional polymeric additive” in claim 5 lacks antecedent basis. Applicants have amended claims 4 and 5 accordingly.

The Examiner rejected claims 1-8 and 10 under 35 USC 102(e) as anticipated by Elliot, and claims 9 and 11 under 35 USC 103(a) as being unpatentable over Elliot alone.

However, Elliot does not disclose or suggest a blend which forms a highly radiopaque yet relatively flexible radiopaque marker, wherein the radiopaque particles are the only metal present in the marker, as required by the embodiment of Applicant's claim 1. Rather, Elliot requires that the tungsten-organic binder blend includes a second metal having a high packing density. Support for the amendment to Applicant's claim 1 can be found at paragraphs [0017], [0027] and [0030] describing an example blend (in which a blend composition having 91.3 weight percent tungsten forms a marker having a general fill ratio of 91.3 weight percent).

Although Elliot does disclose a high fill ratio of tungsten in a polymer binder, Elliot is directed to providing a lead replacement having similar density as lead and with reasonable formability coupled with structural rigidity (see, paragraph [0013]). In contrast, Applicant's invention is directed to a radiopaque marker for an intraluminal medical device formed of a radiopaque polymer blend with high radiopacity yet high flexibility. As discussed in Applicant's specification (see e.g., paragraphs [0007] and [0012]), a radiopaque marker of the invention provided on a medical device shaft preferable has little affect on the flexibility of the shaft. Although Elliot discloses that the blend is shapeable (Elliot discloses at paragraph 0056 that the blend/composite "has an excellent combination of density, processibility and malleability (deformation on impact)'), because Elliot is directed to maximizing the density of the blend, Elliot requires the inclusion of the second metal, irrespective of the flexibility of the finished

product. Thus, although the blend of Elliot can be deformed on impact into a desired final shape, Elliot does not disclose or suggest a tungsten-polymeric binder blend in which the radiopaque particles encapsulated in the polymer are the only metal present such that the resulting marker is highly radiopaque yet highly flexible.

Moreover, to the extent Elliot is understood, Elliot does not disclose or suggest limiting the maximum particle size of the radiopaque particles (i.e., tungsten powder) as required by Applicant's claim 1, which requires that the radiopaque particles have a maximum diameter of about 20 microns. Although Elliot does disclose that the tungsten powder has a mean particle size which is preferably about 0.5-50 microns, more preferably about 1-50 microns, more preferably still 2-20 microns and more preferably still 1-10 microns, Elliot does not disclose that the maximum diameter of the tungsten particles is about 20 microns in combination with an average diameter of at least 2 microns, and therefore does not disclose every element of Applicant's claim 1 as required for a rejection under 35 USC 102.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

FULWIDER PATTON LLP

By:



Gunther O. Hanke
Registration No. 32,989

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201